No. 83-196

In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
APPELLANT

v.

MONSANTO COMPANY

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF MISSOURI

REPLY BRIEF FOR THE APPELLANT

REX E. LEE
Solicitor General
Department of Justice
Washington, D.C. 20530
(202) 633-2217

TABLE OF AUTHORITIES

In the Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
APPELLANT

v.

MONSANTO COMPANY

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF MISSOURI

REPLY BRIEF FOR THE APPELLANT

Appellee's generalizations about the commercial importance of trade secrets and the extensiveness of its research activities are not responsive to the particular uses made of testing data in the FIFRA registration scheme or to the limited nature of FIFRA's public disclosure requirement. Similarly overdrawn are appellee's analogies to cases involving physical invasion of real or other tangible property or the expropriation of liens, contract rights or other intangibles representing discrete entrepreneurial transactions. The health and safety information at issue here is not developed for marketing as a separate commercial product, but instead is a component part of an effort designed to culminate in the development and marketing of a pesticide. Appellee's ability to manufacture and market that product is fully preserved under FIFRA. Accordingly, appellee has

not been deprived of the primary means of commercially exploiting its endeavors. To the extent the provisions at issue impede the possibility of appellee's developing a secondary market for the data themselves, such a market would largely be a creation of FIFRA's own registration requirements and is, in any event, properly subject to diminution resulting from Congress's regulatory efforts to enhance health and safety protections in the marketing and use of pesticides.

1. Appellee points out (Br. 31) that if FIFRA were repealed altogether and registration of pesticides were no longer required, "[r]esearch and testing at Monsanto would necessarily proceed * * *." In that event, however, any competitor would be free to market copies of Monsanto's unpatented end-products, without any necessity of duplicating Monsanto's testing or gaining access to its testing data. And, hypothetically, instead of enacting FIFRA, Congress could have required registration, supported by testing data, only of new pesticide products, which (if unpatented) could then freely be copied by other manufacturers.[1]

These hypotheticals amply show that, in the absence of FIFRA, Monsanto would have no protection (other than that afforded by the patent laws) against competition in the manufacture of its pesticides.[2] The fact that Congress, in

---

[1]This is the method of accommodating interests in public health, innovation, and competition in the Food and Drug Administration's approval systems for food additives and color additives. These call for premarketing submissions only by the pioneer company; competitors need obtain no approvals before marketing copies of an approved product (21 U.S.C. 348(a)(2); 21 U.S.C. 376(a)(1)). And, "[a]ll safety and functionality data and information submitted" by the pioneer company are "available for public disclosure" (21 C.F.R. 71.15, 171.1(h)).

[2]Trade secret protection of its formulas and manufacturing processes, of course, remains unaffected by FIFRA.

FIFRA, afforded only limited non-patent protection to innovators, by providing them with certain rights to periods of exclusive use and to compensation from competitors for part of the cost of testing, is thus not a diminution, but instead is an enhancement, of the rights against competition that would exist for the innovator in the absence of the statute. This fundamental inconsistency with appellee's "taking" claim should not be allowed to be obscured by reliance on form over substance—*i.e.*, by the mere fact that FIFRA provides this enhanced protection against competition in the form of conditioning the issuance of registrations to competitors based on the innovator's previously submitted testing data. That appellee would prefer the additional (economically inefficient) obstacle of requiring competitors to duplicate the testing does not mean that its property has been taken.

2. FIFRA's provision for disclosure to the consuming public of health and safety data is a narrowly drawn condition on the right to market these potentially dangerous chemical products that is reasonably related to protection of the public health and safety. In *Andrus* v. *Allard*, 444 U.S. 51 (1979), the Court held that the Eagle Protection Act's total prohibition, because of environmental concerns, of the marketing of eagle feathers was not a "taking" requiring compensation. The Court pointed out that appellees retained the right to possess, transport, donate, devise, or exhibit their property, but it recognized that the prohibition (applied by regulation to pre-Act as well as post-Act property) "prevent[s] the most profitable use of appellees' property" (444 U.S. at 66). Here, Congress, in an area of even more comprehensive environmental danger and concern, has preserved the most profitable use of appellee's total endeavor—the manufacture and marketing of the pesticide end-product. In return, in order to enhance protection of the public health and safety from the dangers posed by the

marketing and use of these chemicals, Congress has required a limited disclosure to the consuming public of pertinent health and safety data.[3] The mere fact that appellee can separately label as a "trade secret" its interest in retaining such information should not lead to a different result from *Allard*, which, unlike this case, involved destruction of the most valuable strand of the "bundle" of property rights (444 U.S. at 66).

For these reasons and the reasons stated in our opening brief,[4] the judgment of the district court should be reversed.

Respectfully submitted.

REX E. LEE
Solicitor General

FEBRUARY 1984

---

[3]Although Monsanto (Br. 5-6) points to alleged EPA mistakes in administering the statute, the record shows that EPA has strived to adhere carefully to the statutory limitations on disclosure. J.A. 208, 248-250, 251.

[4]We note that Monsanto expressly agrees (Br. 40 n.56) with our contention that the district court erred in holding the constitutionality of the arbitration and compensation scheme ripe for review. See pages 44-47 of our opening brief.